TESTIMONY OF

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REVIEW OF THE PROPOSED GENERIC DRUG AND BIOSIMILARS USER FEES AND FURTHER EXAMINATION OF DRUG SHORTAGES

BEFORE THE

COMMITTEE ON ENERGY & COMMERCE

SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

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"Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages" – February 9, 2012

Summary of Testimony before the House Energy and Commerce Committee, Subcommittee on Health
Heather Bresch, CEO, Mylan Inc.

When FDA was essentially created through the FDCA of 1938, FDA was equipped as a domestic agency charged with overseeing a domestic industry. Today, the drug industry supplying the U.S. is a global one, but FDA still remains domestic. Congress should update the FDCA of 1938 to equip FDA as a global agency to strengthen the integrity of the supply chain and ensure a level playing field for manufacturers.

- **Current Landscape For Generic Drugs.** Now more than ever, Americans and the government need more timely access to low cost, high quality medicine. The generic drug industry has saved the government, patients and payors more than $931 billion over the last decade alone by reliably providing low cost, safe and effective generic drugs. Recent years have seen a significant increase in the number of applications for generic products, as well as substantial growth in the foreign facilities that support the U.S. drug supply. Unfortunately, FDA's resources have not kept up with this increased workload, and, as a result, the time it takes to get a generic drug approved has nearly doubled in recent years and more than 2,700 applications are currently awaiting FDA approval. Because a recent inspection history is required prior to product approval, the inspection backlog is likewise adding to the long delays in generic approvals.
- **Landmark Generic Drug User Fee Program.** To help provide FDA with supplemental resources to address the challenges caused by globalization of the drug supply chain and the related increase in the agency's workload, the generic drug industry negotiated a landmark generic user fee program ("GDUFA") that provides $299 million annually and is focused on three key aims: **1) Safety** – ensuring that both foreign and domestic industry participants in the U.S. generic drug system are held to the same, consistent, high quality standards and are GMP inspected by FDA biennially using a risk-based approach; **2) Access** – expediting the availability of generic drugs through more timely reviews; and **3) Transparency** – Enhancing FDA's ability to require the identification and registration of all facilities involved in the manufacture of generic drugs.
- **More timely access to Generics Expected to Increase Savings and Lower Health Care Spend.** Generics currently save the government and consumers more than $3 billion each week. GDUFA will provide more timely access to more affordable generics, which is expected to even further lower government and consumer health care spending.
- **Supply Chain Integrity.** One of the key ways FDA oversees continued compliance with the quality standards required of all prescription drugs sold in the U.S. (branded and generic) is by conducting on-site GMP facility inspections. These critical surveillance inspections (known as GMP inspections) ensure that facilities are continuing to meet their obligation of producing safe products in accordance with rigorous current good manufacturing practices and are intended, among other things, to identify potential concerns or observations before an issue emerges or increases in severity so as to later interrupt or impact the safety or efficacy of the drug supply.
- **Pressing Need to Globalize FDA Authority.** Today, 40% of all drugs Americans take are imported and up to 80% of the active pharmaceutical ingredients in those drugs come from foreign facilities. FDA's GMP inspections have not kept pace with the exponential growth in foreign facilities that supply the U.S. pharmaceutical market. According to FDA, foreign facilities supporting the U.S. drug supply have grown by 185% while at the same time FDA inspection rates have decreased by nearly 57%. Moreover, the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA") requires American manufacturers associated with pharmaceutical production to undergo a GMP inspection every two years but the law does not require the same of foreign manufacturers, which are inspected every nine years on average.
- **Unlevel Playing Field Decreases Competiveness.** The inspection disparity between foreign and domestic manufacturers disadvantages U.S. companies by creating an unlevel playing field that encourages the export of U.S. jobs and holds U.S. manufacturers to higher standards with associated higher costs. Pew reports that it costs 25% more to maintain facilities in compliance with GMP.
- **Delayed Entry of New Generic Drugs.** The infrequency of foreign facility inspections delays approval of new medicines, including generics. The inspection disparity also disadvantages generic drug applicants, particularly foreign applicants as well as small and first time entrants who are delayed in obtaining approvals for new products due to a lack of a recent inspection history which is required for approval.
- **Authority Needed to Modernize FDCA.** The generic drug industry, which represents 78% of the U.S. drug supply, will provide FDA with most of the supplemental resources it needs to conduct biennial GMP inspections on a risk-adjusted basis under GDUFA. We urge Congress to update the FDCA to give FDA the legal authority it needs to level the playing field for inspection parity and ensure FDA is equipped by law to carry out its mission in overseeing a global drug supply chain.
- **Drug Shortages.** An important benefit of GDUFA is that potential weak links in the supply chain can be identified and addressed as early as possible through routine GMP surveillance inspection to prevent supply disruptions. GDUFA's decreased review times will ensure more timely access to new generic products, including those that address an unmet medical need or those in short supply.
- **Biosimilar User Fees.** User fees for biogenerics have been developed in accordance with the mandate provided under the Affordable Care Act. However, much work beyond user fees remains to be done to develop a workable pathway that generates the expected savings to Americans and provides access to more affordable generics.

I. INTRODUCTION

Good morning Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee. Thank you for the opportunity to testify today on the Generic Drug User Fee Act program ("GDUFA"), which is jointly proposed by the U.S. Food and Drug Administration ("FDA") and industry, the Biosimilars User Fee Act ("BsUFA"), and the committee's examination of the issues surrounding drug shortages.

I am Heather Bresch, CEO of Mylan Inc., the world's third largest generic and specialty pharmaceutical company and the largest global generics company headquartered in the United States. I also serve on Mylan's board of directors. I have spent 20 years at Mylan, holding numerous positions across more than 15 areas of our business. Prior to becoming CEO, I served as president, where I was responsible for the day-to-day operations of the company. Before that, I served as Mylan's chief operating officer and chief integration officer, leading the successful integration of two transformational international acquisitions – Matrix Laboratories and Merck KGaA's generics business. In addition, I served as head of Mylan's North America operations. I also served two consecutive terms as chairman of the Generic Pharmaceutical Association and one term as its vice chairman. Over the course of my career, I have been a strong advocate of initiatives and policy changes aimed at removing barriers that hinder patient access to high-quality medicine.

II. BACKGROUND

Mylan was founded 50 years ago in White Sulphur Springs, West Virginia and for the first 45 years of our history, Mylan only served the U.S. market. Realizing that we would need to expand our footprint to produce the needed scale and reliable quantities of high quality medicine to compete in our now global drug industry, Mylan has now transformed from a purely domestic company into a global one over the last five years.

Today, we provide products to customers in more than 150 countries and territories and have a global workforce of more than 18,000, including over 5,000 employees in the U.S. We maintain one of the industry's broadest and highest quality product portfolios, with more than 1,000 separate products across more than 20 disease states, supported by a robust product pipeline.

We also operate one of the world's largest active pharmaceutical ingredient manufacturers, and run a specialty pharmaceuticals business focused on respiratory, allergy and psychiatric therapies. Today, one out of every 11 prescriptions dispensed in the United States, brand or generic, is a Mylan product. In addition to our multiple U.S. facilities, including our largest facility in Morgantown, West Virginia which produces nearly 20 billion doses of medicine on average each year, Mylan now has multiple facilities outside the U.S. that supply the U.S. market. All of our facilities that supply the US market have been inspected and measured by the same high quality standards of FDA.

We are proud of the investments we make in all of our facilities around the world to deliver quality products. We also are proud of our role in providing

patients with access to more affordable medicine, particularly here in the United States, where the generic drug industry has collectively provided more than $931 billion of savings over the last decade as a result of the use of high quality generic prescription drugs in place of brand name counterparts.[1] Today, 78% of all prescriptions dispensed in the United States are generics.

As we have expanded our domestic based structure to reflect our now global footprint, Mylan quickly discovered that while we and much of our industry are now global, FDA is still effectively operating as a domestic agency that is not equipped with the resources or legal authority to regulate the global drug supply that now serves the U.S. market. Indeed, FDA is governed by an antiquated law, the Federal Food, Drug and Cosmetic Act ("FDCA"), key sections of which have not been updated since its passage in 1938 when the U.S. operated almost entirely as a domestic pharmaceutical market. As currently written, the FDCA does not properly equip FDA with the authority it needs to carry out its mission in the now globalized U.S. pharmaceutical supply chain. For example, current law requires that U.S.-based manufacturers be inspected by FDA every two years, but does not require the same of foreign manufacturers.

We also discovered that FDA resources have been far outpaced by a significant increase in workload, generated by a dramatic increase in abbreviated new drug applications and exponential growth in foreign facilities supplying the U.S. pharmaceutical market. Given that FDA operates under a legal requirement to inspect U.S. facilities bi-annually and that the law is silent on foreign facilities,

[1] "An Economic Analysis of Generic Drug Usage in the U.S." Independent Analysis by IMS Health, Sept. 2011.

FDA has deployed the vast majority of its resources domestically. The end result is an unlevel playing field for U.S. manufacturers, different quality standards for products sold in the U.S. based on where they were manufactured, and a significant delay in FDA review times of generic drug applications, with a backlog of more than 2,700 abbreviated new drug applications, and many awaiting a recent inspection history before approval can be granted.

Just as the pharmaceutical industry has transformed into a global one, in order to meet its mission, so too must FDA. To that end, with a 50-year history of working closely with the FDA, Mylan is pleased to have played a leading role in developing and negotiating a comprehensive user fee program for generic drugs, along with our colleagues across the generic and API industries.[2] The GDUFA program helps address FDA's challenge of carrying out its mission in the face of a global drug supply chain and providing patients with more timely access to more affordable, safe and effective medicine.

GDUFA recognizes that while providing earlier access to effective medicines is critical (the key aim of all other existing user fee programs), an equally important pillar of FDA's mission is ensuring the safety and integrity of the drug supply. As a result, in addition to expediting access to more affordable, high quality generic drugs, the key goals of the Generic Drug User Fee Program described further below include holding all industry participants contributing to

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[2] *See* Mylan Inc. Submissions to Docket No. FDA-2010-N-0381 proposing a holistic user fee program dated October 17, 2010 and Testimony before FDA to discuss generic drug user fees, September 17, 2010. *See also* Matrix Laboratories Limited (subsidiary of Mylan Inc.) Submission to Docket No. FDA-2010-N-0381 dated March 30, 2011.

the U.S. generic drug system, foreign and domestic, to the same rigorous GMP inspection standards and enhancing FDA's ability to identify, track and register all facilities involved in each generic drug sold in the U.S. [3]

Through GDUFA, the generic industry, which as I noted represents more than three fourths of all prescriptions dispensed in the U.S., will provide FDA with approximately $1.5 billion in new funding over the next five years. In return, FDA has agreed to more timely review of generic drug applications (i.e., by year 5 of the program, 90% of abbreviated new drug applications ("ANDAs") will be at 10-month complete review times), increased transparency, and biennial GMP surveillance inspections of all generic finished dosage form ("FDF") and active pharmaceutical ingredient manufacturers ("API") – foreign and domestic – on a risk adjusted basis.[4]

However, while this funding will help FDA make significant progress in addressing critical industry-wide issues, there is more that Congress can do to help address the issue of supply chain integrity. In order to truly eliminate the disparity between foreign and domestic facility inspection rates, create a more level playing field for U.S. manufacturers, and better ensure the safety of the global supply chain, we join the Generic Pharmaceutical Association ("GPhA") in

[3] Although GDUFA requires FDF and API manufacturers to both pay respective fees and register as part of the generic drug user fee program, GDUFA requires all other generic drug program participants to register even though such participants are not responsible for a fee through Sept. 31, 2017 under GDUFA.

[4] *See* GDUFA goals letter for further explanation of risk basis. *See also* GPhA's testimony before the Senate HELP Committee, dated Sept. 17, 2011. (A "risk-based" model for inspections prioritizes inspections according to a company's safety and compliance track record. This system would ensure that questionable or problematic facilities receive a comprehensive review and evaluation sooner. Facilities with strong records of compliance and positive inspections would be placed further down on the inspection schedule, allowing the agency to prioritize its immediate attention on companies that have never had an inspection or that have a history of compliance issues.)

urging Congress to amend the FDCA to reflect the inspection model being established by GDUFA, thus modernizing FDA's existing authority to reflect the needs of the current 21st century global drug supply.

As part of a Special Report issued by FDA in July 2011, entitled *Pathway to Global Product Safety and Quality,* FDA outlined its plan to "transform itself from a domestic agency operating in a globalized world to a truly global agency fully prepared for a regulatory environment in which product safety and quality know no borders." In this report, FDA likewise acknowledged that to carry out its mission in the globalized pharmaceutical market, the agency is "looking to Congress to modernize its antiquated authorities so that FDA's legal tools keep pace with globalization."[5]

III. KEY ISSUES THAT A DOMESTICALLY FOCUSED FDA FACES IN CARRYING OUT ITS MISSION IN A GLOBAL DRUG SUPPLY

A. Challenges caused by global drug supply chain

With a mission to protect and promote the public health, FDA has a critical responsibility, along with industry, to ensure the safety, efficacy and security of the U.S. drug supply. Fulfilling this responsibility today is much more challenging than it was in 1938, when the FDCA was enacted. Back then, most of the pharmaceutical products consumed in the U.S. were produced in the U.S. Today's U.S. pharmaceutical industry is global, highly complex and growing rapidly, considerably outstripping the agency's operating capacity.

Drug products, both branded and generic, originate in factories all over the world, moving into the American marketplace through supply chains that can

[5] FDA, Special Report, Pathway to Global Product Safety and Quality, page 4. (July 2011)

involve numerous processing plants, manufacturers, suppliers, brokers, packagers and distributors. The agency estimates that up to 40 percent of finished drugs consumed by U.S. patients are manufactured abroad and 80 percent of the active ingredients and bulk chemicals used in drugs come from foreign countries.[6] According to FDA, the number of foreign drug facilities supplying the U.S. has grown by 185 percent between 2001 and 2008 while at the same time FDA inspection rates have decreased by nearly 57 percent.[7] Further, the number of FDA-regulated products arriving from abroad has grown substantially. In 2010, nearly 20 million shipments of food, drugs and cosmetics arrived at U.S. ports of entry.[8] A decade earlier, that number was closer to 6 million, and a decade before, just a fraction of that figure.[9] Today, 20 to 25 cents of every consumer dollar spent in the U.S. is spent on an FDA-regulated product.[10]

Despite the globalization of the pharmaceutical supply chain, the U.S. has not modernized the laws governing supply chain integrity or the scope of its regulatory oversight to reflect the reality of the global marketplace. As a consequence, FDA currently has limited de facto oversight of imported drugs, making it effectively impossible to ensure the quality of the nation's drug supply. In addition, FDA's lack of resources threatens the availability of drugs.

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[6] U.S. Government Accountability Office. Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed (Publication No. GAO-10-961). (September 2010).
[7] Deborah M. Autor, Deputy Commissioner, U.S. Food and Drug Administration, *Ensuring the Safety, Efficacy, and Quality of Drugs*, A Roundtable on Ensuring the Safety of the U.S. Drug Supply, Mar 14-15, 2011.
[8] Remarks of Margaret A. Hamburg, M.D., Commissioner of Food And Drugs at Center for Strategic and International Studies (February 4, 2010)
[9] *Id.*

Importantly, American manufacturers are being disadvantaged versus foreign competitors who do not face the same stringent – and costly – manufacturing and quality standards applied to U.S. companies.[11] In order to compete in the global marketplace, some U.S. pharmaceutical manufacturers actually have a perverse incentive to move existing U.S. jobs abroad, where they will face less regulatory scrutiny than those manufacturing in the US. These issues will only be addressed through modernization of U.S. law and the provision of resources necessary to fully fund the FDA's oversight of today's complex and global drug supply.

IV. THE GENERIC DRUG INDUSTRY HAS STEPPED UP TO THE PLATE TO ADDRESS INDUSTRY WIDE ISSUE

A. Generic Drug User Fee Act ("GDUFA")

Given the significant challenges FDA faces in carrying out its responsibility, the substantial growth in applications and facilities requiring FDA review and oversight, as well as the need for a recent inspection history before a new product can be approved, the generic user fee program is focused on helping the agency holistically achieve the following key aims:

Safety – Ensuring that generic industry participants, foreign or domestic, who participate in the U.S. generic supply are held to consistent high quality standards and are GMP inspected every two years, using a risk-based approach, with foreign and domestic parity.

[11] *See generally,* Pew Health Group, After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs.

Access – Expediting consumer access to generic products by improving timeliness in the review process and providing greater predictability to the application review process to encourage additional innovation.

Transparency – Enhancing FDA's ability to protect Americans in the complex global supply environment by identifying and requiring the registration of all facilities involved in each generic product in the U.S., and improving FDA's communications and feedback with industry in order to expedite product access.

Historically, the generic industry has not used a fee program to provide funding to the FDA review process, as the brand drug and medical device industries have. However, as I described, FDA's current resources have not been adequate to manage the expanding workload caused by an increase in both the number of ANDAs and the number of facilities, with the most growth coming from foreign facilities supporting those applications. The FDA has acknowledged that delays in foreign inspections have contributed to delays in generic drug approval times because facilities listed in applications lack a recent inspection history, which is required before a new generic drug application may be approved. Over the last several years, the review and approval time for an ANDA has nearly doubled. Currently, it is estimated that over 2,700 ANDAs are now awaiting FDA review and the average review time for an ANDA is nearing 32 months.

The delay in approval time also undermines the 180-day exclusivity Congress provided under the Hatch-Waxman Act to incentivize companies to take on the substantial litigation risk associated with such patent challenges in

order to get more affordable prescription drugs into the hands of consumers before patents expire. Under current law, if an applicant does not obtain tentative approval of its ANDA within 30 months of filing, that applicant will lose this vital 180-day exclusivity. The original intent of the forfeiture provision, which was written when the average ANDA approval time was at 16 months, was to ensure that ANDA applicants actively worked toward approval. With the average review time now 32 months, the 180-day exclusivity incentive is significantly threatened through no fault of the ANDA filer.[12]

The generic drug user fee program calls for a broad range of participants in the generic drug industry to contribute $299 million, adjusted annually for inflation, for each of the five years of the program starting October 1, 2012, which will supplement appropriated funds. In order to ensure that patients, payors and the government continue to benefit from the significant savings offered by generic drugs, representing an average of $3 billion in savings each week, it was imperative to the industry and FDA to design a program that would keep the individual fee amounts as low as possible.[13] The total amount of funding from the generic industry will be drawn from a broad funding source, including an estimated 2,000 FDF and API manufacturers supporting ANDAs, prior approval supplements (PASs), and drug master files (DMFs) as well as application fees which cover ANDAs, PASs and DMFs.

[12] GDUFA includes an expedited review of first to file Paragraph IV ANDAs during the first two years of the program (before reportable review metrics apply starting in year 3) in an effort to minimize inadvertent forfeiture risk for failure to obtain a tentative approval within 30 months of submission.

[13] "An Economic Analysis of Generic Drug Usage in the U.S." Independent Analysis by IMS Health, Sept. 2011.

The fee package is structured so that 80 percent of the total will be derived from the FDF industry and 20 percent from the API industry. The variety of funding sources for the program will assure that participants in the generic drug industry, whether FDF or API manufacturers, appropriately share the financial expense and benefits of the program. Of the majority of the total generic drug user fee package, 70 percent will be derived from facility fees, while the remaining 30 percent shall be derived from application fees. Both FDF and API manufacturing facilities listed or referenced in a pending or approved ANDA will pay a facility fee. Foreign facilities will include a modest fee differential to reflect the average additional costs of foreign inspections based on data determined by the agency.[14] The remaining 30 percent of the total generic drug user fee package will be derived from application fees. Application fees include an ANDA, PAS, and DMF application fee. In addition, in the first year of the program there will be a one time backlog fee for ANDAs that are pending on October 1, 2012, and have not received tentative approval.

In return for the fees, the industry and FDA have agreed upon a number of additional goals, metrics, and efficiencies set forth in detail in a negotiated goals letter. Importantly, with these resources, FDA has committed to, among other metrics: (1) review and act on 90 percent of new ANDAs within 10 months from submission; (2) act on 90 percent of all ANDAs and PASs that are pending in the backlog (an estimated 2,700 applications); and (3) achieve parity of GMP

[14] According to FDA's *Pathway to Global Product Safety and Quality* Special Report, Exhibit 10, published in 2011, the average cost of foreign inspections ($52,000) is two times the average cost of a domestic inspection ($23,000).

inspections for foreign and domestic facilities by the fifth year of the user fee program.

Notably, given that many facilities make both brand and generic products, it is expected that the generic drug program will pay for biennial, risk-based GMP inspections of FDF and API facilities representing more than 78% of the total U.S. pharmaceutical market, including both brand and generic products.

Mylan is proud of all that GDUFA will accomplish, and the historic paradigm shift that it establishes. The generic industry, which accounts for 78 percent of all prescription dispensed in the U.S. has stepped up to the plate to help provide FDA with resources to address the industry-wide, both branded and generic challenges caused by the global drug supply and the corresponding increase in FDA's workload. However, for it to truly be successful, and to achieve the lasting change that I believe we all wish to see, the currently outdated U.S. law must also be amended to reflect the 21st century needs of the FDA in regulating the nation's global drug supply.

B. FDA's governing law on drug oversight is reflective of the 1938 Pharmaceutical Industry, not today's climate

Every consumer should have the peace of mind in knowing that every prescription, brand or generic, dispensed in the United States, is held to the same standard of quality regardless of whether the product or its ingredients originated in the U.S. or outside its borders. Unfortunately, the current provisions of U.S. law, based largely on FDCA, were passed in 1938 when the source of our drug supply looked quite different than today.

One of the key ways FDA carries out its oversight responsibilities of ensuring continued compliance with the quality standards required of all prescription drugs sold in the U.S. (branded and generic) is by conducting on-site facility inspections. Unlike pre-approval inspections which occur prior to a specific product approval, routine surveillance inspections (known as GMP inspections) ensure that facilities are continuing to meet their obligation of producing safe products after approval in accordance with rigorous good manufacturing practices and are intended to identify potential concerns or observations before an issue emerges that may later interrupt or impact the safety or efficacy of the drug supply. The FDCA requires American manufacturers associated with pharmaceutical production to undergo a routine GMP inspection every two years to ensure that these facilities are complying with rigorous GMP standards.[15] However, the FDCA does not impose the same biennial inspection requirement on foreign facilities. The average GMP facility inspection of foreign facilities occurs every nine years compared to every two years for a U.S.-based facility.[16] According to a 2010 GAO report, the FDA inspected just 11 percent of the 3,765 foreign establishments in its database in 2009. GAO estimates that some foreign facilities supplying the U.S. market may have never undergone a GMP inspection.[17]

C. Unlevel Playing Field that Threatens American Competitiveness

[15] *See* 21 U.S.C. § 360.
[16] U.S. Government Accountability Office. Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed (Publication No. GAO-10-961). (September 2010).
[17] *Id.*

The significant disparity in the degree of FDA oversight experienced by domestic facilities compared to foreign facilities creates an unlevel playing field, reducing the ability of American businesses, which have built in costs for regular GMP compliance, to compete. The U.S. already has the second-highest combined federal-state corporate tax rate, 39.2 percent, and according to a recent report by Pew Health Group, complying with quality systems and FDA regulations represents approximately 25 percent of a drug manufacturers' operating costs.[18] U.S.-based facilities participating in both the U.S. and global pharmaceutical market should not be competitively disadvantaged and effectively encouraged to move jobs to outside of the U.S. as a result of an antiquated law that is impeding FDA from carrying out its oversight responsibilities over all players supplying the U.S. pharmaceutical market.

Mandating FDA risk-based biennial GMP inspections of all facilities, foreign and domestic, will improve quality and create a level playing field for all pharmaceutical manufacturers. Inspection parity will also benefit foreign facilities, as well as small and first time entrants to the industry, which are currently disadvantaged by delays in gaining approval for new products due to a lack of a recent inspection history, which is required before a new product can be approved.

Congress recently updated the FDCA to help equip the FDA to carry out its mission of ensuring food safety in an increasingly globalized food supply.[19] With respect to the global drug supply, however, FDA still effectively operates

[18] Pew Health Group, After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs, at 27.
[19] FDA Food Safety Modernization Act, Public Law 111-353.

within the constraints of the FDCA of 1938, the scope and provisions of which are largely domestic. The agency recently acknowledged that when it comes to drug oversight, FDA is "looking to Congress to modernize its antiquated authorities so that FDA's legal tools keep pace with globalization."[20] Without changes to laws governing the U.S. drug supply necessary to fully fund FDA's oversight of today's complex and global drug supply, the significant challenges to the U.S. pharmaceutical marketplace will continue and likely increase.

Ensuring that all contributors to the U.S. drug system, both foreign and domestic, are held to the same quality standard is a critical issue for the entire pharmaceutical industry – brand and generic alike. Amending the FDCA of 1938, and in particular, mandating risk-based routine FDA GMP inspections of all domestic and foreign pharmaceutical facilities every two years, will improve the quality, consistency and availability of finished product and active ingredients within the drug supply chain.

Additionally, the lack of routine surveillance GMP inspections of foreign facilities has allowed weak links to enter the supply chain, resulting in potential market disruptions or other adverse events. GMP inspections are intended to, among other things, detect and address such quality concerns early in the manufacturing process.

The backlog in routine foreign GMP surveillance inspections also causes notable delays in introducing new prescription drugs to consumers, including delays in approving products that serve unmet medical needs and offer more affordable options such as generic drugs. As I described previously, approval of

[20] FDA, Special Report, Pathway to Global Product Safety and Quality, pg 4. (July 2011)

a drug requires a recent inspection history of the relevant manufacturing facility. Many of the facilities producing new drugs are based abroad and are therefore waiting years to be inspected.

Globalizing FDA by enhancing the law authorizing FDA to oversee today's complex and global drug supply to reflect the significant challenges to the U.S. pharmaceutical marketplace, will allow FDA to respond to the increasing challenges it faces in regulating the nation's drug supply. We urge Congress to move forward in updating the 1938 law and adopting the Generic Drug User Fee Program as negotiated with the FDA and industry.

V. DRUG SHORTAGES

As noted above, an important benefit of the generic drug user fee program is to identify and address potential weak links in the supply chain as early as possible. By conducting routine, on-site surveillance inspections (GMP inspections) of facilities located in the U.S. and abroad to ensure that they comply with rigorous GMP standards, FDA will be positioned to detect market disruptions before they occur. GMP inspections are critical to the Agency's ability to identify potential concerns before an issue emerges that may later interrupt or impact the safety or efficacy of the supply chain. We believe drug shortages could be reduced as FDA achieves parity in GMP inspections of foreign and domestic facilities using a risk based approach. Additionally, the additional resources under GDUFA will decrease review times and ensure more timely access to new generic products, including those that address an unmet medical need or those in short supply. Strengthening the supply chain – a key

aim of GDUFA through routine, GMP inspections as well as transparency initiatives that require the identification and registration of facilities involved in the supply chain – will provide a more holistic solution. To make lasting change, we urge Congress to make the necessary updates to the FDCA of 1938 to give FDA the authority it needs to carry out its mission in today's global drug supply.

VI. BIOSIMILARS USER FEE

The Affordable Care Act of 2010 directed FDA to develop a user fee program for review of biosimilar and interchangeable biological products in an effort to expedite access to biogenerics. Unlike GDUFA, the Biosimilars User Fee Act proposal before you was based on the Biologics Price Competition and Innovation Act (BPCIA), which was passed into law in March 2010 as part of the Patient Protection and Affordable Care Act (PPACA). Therefore, the opportunity to take a holistic approach to this user fee proposal, as the generic industry was able to do with GDUFA, was not available. While user fees were mandated and shaped by the Affordable Care Act in order to help expedite access to more affordable biogenerics, achieving the true savings Americans deserve through more affordable biogenerics will require much additional work and resources from Congress. It is telling that nearly two years have passed since the biogenerics approval pathway was enacted into law, and to date, no biogeneric has been approved by FDA nor has FDA released any meaningful guidance to promote a workable pathway to deliver access to safe and effective biogenerics. This was clearly not the result Congress intended when it was estimated that the biogenerics pathway would save American taxpayers and the federal

government billions of dollars over the 10 years following its passage in 2010.[21] Mylan looks forward to working with Congress, GPhA and other stakeholders in ensuring a workable pathway to make available safe, effective and affordable biogenerics.

VII. CONCLUSION

In conclusion, Mr. Chairman, Mylan urges Congress to pass the Generic Drug User Fee Program as unanimously ratified by industry and update the Federal Food Drug and Cosmetic of 1938. Only by taking these steps can we further reduce government and taxpayer healthcare spending through more timely access to affordable generic medicine; ensure American competitiveness by addressing the unlevel playing field currently faced by U.S. manufacturers through inspection rates that are four times that of foreign competitors; and equip FDA with the authority it needs to carry out its mission of protecting the drug supply chain in today's highly globalized industry.

Thank you. I would be happy to address any questions of the committee.

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[21] *See*, *e.g.*, CBO, H.R. 4872, Reconciliation Act Of 2010 (Final Health Care Legislation), Cost Estimate For The Amendment In The Nature Of A Substitute For H.R. 4872, Incorporating A Proposed Manager's Amendment Made Public On March 20, 2010, *available at* http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf